Independent Assessment of the LANL Bioassay Program to Determine the Effectiveness of the Corrective Actions Detailed in Noncompliance Report NTS-ALO-LA-LANL-LANL-1997-003 Routine Pu Bioassay Program Weakness

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Executive Summary:

A limited two-day onsite LANL assessment was conducted to independently verify that the corrective actions identified relative to the Noncompliance Report NTS-ALO-LA-LANL-LANL-1997-003 entitled "Routine Pu Bioassay Program Weakness" had been implemented and to a lesser degree evaluate the effectiveness of their implementation. Through the investigatory process, a cursory evaluation of the CST-7, CST-9 and CST-11 radiobioassay services conducted under an Analytical Services Agreement was performed.

The findings of the two-day assessment were summarized and verbally presented at the assessment exit meeting that was conducted at 4:00 p.m. on Friday, September 25, 1998.

Based on the documentation reviewed and interviews conducted, it can be concluded that as of September 30, 1998, the original seven correction actions identified in the Noncompliance Report NTS-ALO-LANL-LANL-1997-003 have been fully addressed and fully implemented. The implementation of the corrective actions has initiated the development of certain interdivisional management plans and program changes, the development of an analytical services agreement defining performance specifications, the need to update certain divisional procedures, policies, measurement assurance requirements and program documentation requirements and the initiation of a schedule for DOELAP participation. These development efforts need further progressive refinements, definition, improvements, formalization or standardization of programs or policies and completion of scheduled commitments. These changes, in some cases, reflect the changes occurring to define a more "true" client and service organization relationship, or an interdivisional project with defined responsibilities and authorities, and the need to clarify the roles, responsibilities, expectations and deliverables of the various organizations / parties. The staff of CST and ESH has recognized this new client - service organization concept and the need to adjust, through either program, policy or procedural changes and to meet their responsibilities under this new concept. The staff must continue to ensure full implementation of programs (with refinements) and schedules outlined in the corrective actions over the next 18 months.

The CST technical programs and radioanalytical processes are excellent. The staff is very technically competent and has an appreciation of and dedication to the metrological process. The radioanalytical data provided to ESH is reliable and has measurable quality. Effort is being made to demonstrate competence and quality through better documentation of existing programs and the update of policies and programs that have been more indicative of a research atmosphere. Documentation of demonstrated competence and quality will be key to DOELAP and client assessments of CST. A more consistent training program and staff proficiency requirements for the CST groups need to be implemented and documented. Better formal and routine feedback to ESH for internal QC and external performance evaluation programs is needed as part of this demonstrated quality.

Additional defined quality performance specifications should be developed and incorporated in either the Analytical Services Agreement, the CST Quality Assurance Plan or CST Quality Assurance Project Plan for the ESH Bioassay work. Quality performance specifications such as bias and precision for the radioanalytical services should be developed and incorporated into the appropriate documents. Ms. D. Lewis and S. Wagner have been doing an excellent job in ensuring the corrective actions have been addressed and program changes are defined and implemented. Continued divisional management level support of their efforts and insights will be essential to the success of the radioanalytical component of the LANL Bioassay program. The quality aspects will be coordinated with the QA Officer, P. Lindahl. This position should have a direct communication line to CST division management or should be a division level position.

Introduction

At the request of William Eisele of ESH-12, a limited two-day onsite LANL assessment was conducted to provide an independent verification of the completion of the corrective actions defined and addressed related to the Noncompliance Report NTS-ALO-LA-LANL-LANL-1997-003 entitled "Routine Pu Bioassay Program Weakness" and to perform a cursory evaluation of the CST-7, CST-9 and CST-11 radiobioassay services conducted under an Analytical Services Agreement. The main intent of the assessment was to document, through an independent third party, that the corrective actions for the original seven noted deficiencies in the nonconformance report had been properly addressed and implemented.

Through the coordination of Dawn Lewis and William Eisele of ESH-12, an onsite LANL assessment was conducted September 24 and 25, 1998. An initial pre-assessment meeting with the cognizant staff from CST and ESH was held at 8:00 a.m., Thursday, September 24. The intent of the assessment and the details of the deficiencies and corrective actions of the noncompliance report were discussed by the CST Division leader. Three additional related corrective action items were added to the original seven items to be reviewed.

Sandra Wagner of CST-7 and Dawn Lewis of ESH-12 were assigned to act as liaisons for my technical assessment. The assessment process involved the review of documentation related to the corrective actions, interviews with cognizant CST technical staff and managers, walk through surveillances of TA-48 and TA-59 radioanalytical operations and facilities, review of previous CST technical assessments, review of CST applicable procedures, review of the CST Bioassay

Project Management Plan and ESH - CST Analytical Services Agreement, review of external performance evaluation programs and spot checks of CST data packages for completeness. A tentative meeting schedule was developed by Dawn Lewis. An assessment exit meeting was scheduled in the conference room of TA-44 for Friday, September 25, 1998 at 4:00 p.m.

Assessment Report

The assessment report consists of specific comments relative to corrective actions items identified in the Noncompliance Report NTS-ALO-LA-LANL-LANL-1997-003 entitled "Routine Pu Bioassay Program Weakness." Summarized below are the individual assessments of completion and effectiveness of the corrective action established or implemented.

Item 1. The responsibilities and authorities for the LANL Bioassay Program will be defined and implemented. This will be conducted jointly with CST Division.

Findings.

This item was initially addressed through the issuance of a document entitled "Responsibilities and Authorities for the LANL Bioassay Program" dated November 3, 1997. The document, signed by Dennis J. Erickson, ESH Division Director and F. Ben Wampler, CST Division Director, was reviewed and found to be of sufficient detail. The document addressed the responsibilities of the ESH and CST Division offices, ESH-12 Group Leader, CST Analytical Services Group Leaders, ESH-12 Dosimetry Services Team Leader and the CST Bioassay Program Leader.

The responsibilities and authorities for the LANL Bioassay Program have also been included in a recently implemented document entitled "Project Management Plan for the CST Bioassay Project - Analytical Services for ESH-12." The issuance date for the Project Management Plan was July 14, 1998. Copies of the plan have been distributed to the cognizant CST and ESH staff involved in the CST Bioassay Project. Random interviews with the document holders, including cognizant managers and points of contact within CST, were conducted to determine their awareness of the Project Management Plan, their involvement in the implementation of the plan and the physical location / possession of the document. The CST staff contacted included D. Dry, W. Efurd, P. Lindahl, G. Brooks and E. Gonzales. Each individual had the latest hard copy plan and was knowledgeable in the planÕs content and his responsibilities in its implementation. The individuals were cognizant of how they would handle formal changes in the plan in terms of how the changes would affect his technical function as well as the analytical, record keeping and documentation procedures.

This item has been fully addressed and is considered closed.

The following comments are made relative to the CST Project Management Plan (PMP)

1. The document is well written and organized. The document is considered to be a living document wherein changes in the plan will reflect changes in the functional or technical areas, recognized improvements or additional clarifications of responsibilities or deliverables.

2. Responsibilities and lines of authority and communications are clearly delineated by functional title. Three key communication and interaction positions for this project are the ESH-12 Dosimetry Services Team Leader, Dawn Lewis; CST Bioassay Project Leader, Sandra Wagner; and the CST QA Team Leader, Peter Lindahl. Based on a limited interaction, Ms. Lewis and Ms. Wagner have been found to be highly qualified, knowledgeable, communicative, dedicated, energetic and very personable. Ms. Lewis and Ms. Wagner were the major developers of the Project Management Plan. There is frequent informal communication between the two and formal monthly meeting to review the provided bioassay services and critical program elements.

3. Although P. Lindahl is a recent appointment to the QA Team Leader (QA Officer) in CST-9, he has extensive experience and technical knowledge in the QA functions and bioassay discipline. Based on industry standards, federal agency requirements and CST procedure QA-1, R.1, the QA Officer "is independent of cost and schedule and has direct access to management at the level where actions originate." In addition, the QA Officer cannot be involved in the routine analytical processing of samples. Therefore, it is recommended that the reporting lines, either directly or indirectly, be to the CST Division Office level.

4. The responsibilities of the project work flow by CST group has been defined and an overview of radioanalytical processes, data package reviews and LIMS interactions provided.

5. The Bioassay Analytical Services Agreement (ASA) between CST and ESH-12 that defines the requirements, products and services to be provided by CST for 1998 has been included as Appendix 1 within the plan. A discussion re the ASA is presented under Item 2.

6. The regulatory and basis documents are well defined and referenced.
A change order and control mechanism has been established to address changes to the Project Management Plan document or appendices. The CST Bioassay Project Leader is responsible for the update, maintenance and distribution of the PMP and for the conduct of periodic reviews to ensure that changes have been implemented. Appendices 4 and 5 of the PMP contain the specific paperwork associated with a formal change in either the ASA and the PMP. The change control mechanism has been well planned and, for the magnitude of the project, should prove effective without a formal controlled document program. If it is found that the PMP is not being kept current at the CST manager or POC level, a controlled document program may prove worthwhile.

The Project Management Plan incorporates, as Appendix 2, the QA plan for the CST Bioassay Project. The QA Plan identifies the applicable quality requirements of the CST Bioassay Project as defined in the Project Management Plan. The key elements of a QA plan as defined 10 CFR 830.120 have been addressed and incorporated into the document. However, more definitive quality performance specifications and program control elements as related to the operation of a radioanalytical laboratory should be incorporated into the QA plan, the Analytical Services Agreement or the CST QA plan. ANSI N42.23-1996 (Measurement and Associated Instrumentation Quality Assurance for Radioassay Laboratories) does provide guidance relative to the key elements that should be addressed in a radioassay QA plan and program. Although the

QA plan should address all aspects of the radioassay laboratory, a priority to establish bias and precision quality performance criteria for CST analytical services should be established.

Personnel training and qualification requirements are discussed in the QA plan. Discussions relative to how the staff is trained and qualified with the CST managers and POCs of CST of TA-48 and TA-59 have revealed an inconsistency of application of training policies between the two groups. The policies for staff training, qualifications and training documentation for the two groups should be consistent. Documentation of staff training and qualification is essential to demonstrating a quality operation. Staff should be qualified through proficiency examinations to demonstrate that they are qualified to analyze samples in conformance with established bias and precision quality performance criteria. The QA plan and CST Analytical Chemistry Procedure QA-1, R.1 entitled "Analytical Chemistry Quality Management Plan" require that "Personnel shall be trained and qualified to ensure they are capable of performing their assigned work." In addition, the objective of the Personnel Training and Qualification (Section 2.1 of QA-1, R.1) is to ensure that those involved in the delivery of analytical information to the client and those who perform the analyses are properly trained and qualified to deliver information and "to perform analyses of a specified quality." As such, it is recommended that quality performance criteria be established and the CST processing staff be qualified through proficiency evaluations (PE samples) to initially demonstrate that the quality of their work is consistent with the quality objectives. The results of the ongoing internal and external single and double blind QC / PE sample programs indexed to the analyst can be used to demonstrate continued proficiency and qualification. As per QA-1, R.1, the development of the training program is the responsibility of the team leader.

A discussion on the CST Bioassay Project Process Flow diagram, as Appendix 3 of the PMP, is provided under Item
5.

A list of quality assurance, quality control and analytical radiochemistry, sample management, QC preparation, instrument operation and computing germane to the CST Bioassay Project Contract were contained within the PMP as Appendix 6. The list has been updated by Sandra Wagner via Revision 1 of the CST Project Management Plan dated September 23, 1998. During the assessment interview process, several procedures from the list were selected at random and cognizant POCs or managers were requested to provide a copy of the procedure used at the bench. The procedures evaluated included: ANC318, R.0, approval date 07/31/98; ANC356, R.0 approval date 03/30/98; and ANC365, R.0, approval date 08/10/98; ANC368, R.0 approval date 05/22/98; ANC1305, R.0 approval date 07/31/98 and QA-8, R.0 approval date 04/29/97. Copies of the procedures provided by the CST staff were consistent with the latest revision and approval dates documented in the PMP, revision 1. Based on the abbreviated spot review, it appears that procedure control is in place. During the interview process at CST-9, the original hard-copy procedures and previous revisions were verified to be controlled under security by CST-9 at TA-59. The original QA-1 through 13 series procedures were relocated to another area during the recent LANL reorganization and the reassignment of Margaret Gautier. Copies of the original QA-1 through 13 series procedures should be obtained and filed with the other original hard copy procedures under security at TA-59. Upon review of the procedures from CST-7, CST-11 and CST-9, there appears to be some inconsistencies in the approach to develop the techniques.

In some cases, the analytical chemistry and nuclear instrumentation counting and applied calculational equations are contained in a single procedure and in other cases several stand-alone procedures have been written to cover the same content. When the samples are being handled or processed as per the Bioassay Program Process Flow Diagram, each stand-alone procedure should reference other associated procedures in the process; either all the other procedures in the process stream or the procedures covering the processes immediately before and after the procedure under review. Typically, the final condition of a procedure indicates that the samples have been received from the previous process (sample receipt, sample prep, etc.) have been processed according to the procedure under review and then sent to the next sample processing step (counting, sample storage, record keeping, etc.)

Item 2. The FY98 Analytical Support Agreement for the Bioassay Program will be formalized and implemented.

Findings.

The Bioassay Analytical Services Agreement (ASA) between CST and ESH-12 that defines the requirements, products and services to be provided by CST for 1998 has been included as Appendix 1 within the CST Project Management Plan. The original analytical services agreement for FY98 was put in place under contract # ESH-12-ACH-98.01 dated November 3, 1997. Revision 1 of the contract for FY98, dated July 15, 1998 has been implemented and distributed to the PMP document holders. The analytical service agreement is very extensive and detailed covering the general program evaluation measurements, production specifications within the scope of work (analytical requirements and detection sensitivity requirements) and quality assurance / quality control requirements, sample processing priorities (turn around times), cost schedule and data deliverables (electronic and hard copy data specifications). Revision 1 to the contract refers to or references, in the QA/QC Requirements Section, the CST Bioassay Project Quality Plan and the CST Bioassay Project Management Plan for the quality assurance aspects over the Bioassay Program. In addition, this revision (item 10) stipulates that all required analytical services will have formal, approved analytical procedures in place as quickly as possible but no later than July 1, 1998. Under the contract revision, the CST program evaluations will be conducted three times in FY98. No assessment was made as to completion or status of the dated commitments documented in the revision of the ASA. Two items should be considered for inclusion in the ASA. First, it is recommended that quality performance criteria for bias and precision be established by ESH and incorporated into either the ASA (or the Bioassay QAP and referenced in the ASA). The quality performance criteria should be more restrictive than the DOELAP (or N13.30-1996) quality acceptance criteria for in vitro radiobioassay. Secondly, there should be requirements in the ASA for CST to routinely (semiannual or annual) provide a summary reporting to ESH of internal batch QC results and to have a feedback mechanism for the results of all external QC or PE programs. CST should look into the development of a quality indicator database for internal batch QC results that can be made available to ESH on a full time, read-only access basis. In addition, ESH and CST should jointly develop corrective action implementation set points for the internal batch QC results.

Item 3. Acceptance criteria for bioassay data being provided by the radiochemistry analysis process will be developed and approved. This will be conducted jointly with the CST Division.

Findings.
Acceptance criteria, in the form of electronic data deliverable specifications, have been incorporated into the ASA as an attachment. The specifications were written jointly by Guthrie Miller (ESH-12) and Donivan Porterfield (CST-3) and dated October 31, 1997. The "specifications" document provides the requirements for the specific fields/components for each analyte and technique, a description of the field/component, and the required formula for calculated fields/components. In essence, an essential link has been established between the electronic data base and the analytical computer programs containing the equations to calculate the various analyte and sample processing parameters. The acceptance criteria are well thought out and of such detail to avoid confusion or misinterpretation. It should be recognized that changes to the basic analytical procedures, equations used or calculations may require concomitant changes to the electronic data deliverables and acceptance criteria.

Items 4 & 8. The resolution of the remaining FY97 bioassay data will be completed.

Findings.

Peggy Gautier, CST-3, issued a memo on October 31, 1997 to Alverton Elliott entitled "Response to Price Anderson Noncompliance Report on LANL Bioassay Program (NTS-ALO-LA-LANL-1997-0003; Correction Action 4. The resolution of the remaining FY 1997 bioassay data will be completed." Within the memo, Ms. Gautier outlined two plans to address this corrective action: a "Plan to Complete the Plutonium Bioassay Sample Backlog-Chemistry and a "Plan to Complete the Plutonium Bioassay Sample Backlog-Data Correction and Rereporting." The plans were very aggressive, well-planned and thorough. The first plan dealt with the scheduling of radiochemistry and TIMS processing of backlogged plutonium priority 3 bioassay samples to meet a December 12, 1997 deadline - not having samples in the alpha analyses system that are over 30 days old. In addition, a second TIMS instrument had been updated for bioassay processing to address the TIMS sample backlog. The second plan dealt with the implementation of the Generic RAS result plan specified in Acceptance Criteria data, the initiation of corrections, validations and certifications of results, and the revisions to the CST*LIMS. The resolution of the remaining FY97 bioassay data was completed by Peggy Gautier and documented in a memo (CST3/PAAA_Corr_ction 4.1) issued to Alverton Elliot dated December 11, 1997 entitled "Response to Price Anderson Noncompliance Report on LANL Bioassay Program (NTS-ALO-LA-LANL-1997-0003; Correction Action 4. The resolution of the remaining FY 1997 bioassay data will be completed." Ms. Gautier had verified that all FY97 plutonium bioassay samples had been reported to ESH-12 as of December 11, 1997. In addition, FY98 plutonium samples due through December 10, 1997 had been reported. The memo references a corrective action request that was issued (CAR# 97.020) to have an audit performed on all hard copy data packages for bioassay submissions for the FY 97 time period to verify that all data packages are complete with the appropriate raw data and final reports. A list of the applicable RAS and TIMS samples was provided. This corrective action request was addressed by Linda Willis and closed on January 28, 1998. On January 27, 1998, Ms. Willis reported to Ms. Gautier that the hard copy data packages for all sample submissions from the list provided were complete with raw data and reports. A root cause analysis report outlining the problem, root cause and proposed actions was completed by Ms. Willis and Ms. Gautier on January 29, 1998. The root cause analysis of the problem for the backlog of data reporting was

detailed and insightful. The majority of the root causes listed stem from non-radioanalytical issues that include program management planning and transition to a new LIMS. The proposed corrective action of including an electronic data field in the electronic deliverables for the QA officer sign off should facilitate the rapid verification that data packages / reports have been reviewed, signaturized and archived. During the program assessment of CST-11, D. Lewis and D. McCurdy performed a spot check on several archived data packages for FY98 sample analyses for plutonium and uranium. The data packages were reviewed for completeness as per the ASA requirements; to include a case narrative, service agreement, final data report, laboratory bench sheets, documentation of CST chain of custody, spectral and channel outputs, individual counter efficiencies and background, reference to documentation of evidence of NIST traceability calibration standards, reference to documentation of evidence of pipet and balance calibration, reference to documentation of the most recent applicable MDA study results, initial calibrations and re-calibrations and procedure reference to all equations used to calculate MDA or sample results. The data packages reviewed appeared to be adequate but certain inconsistencies were noted in the information reported by TA-48 and TA-59. The inclusion of an alpha spectrometry pointer sheet and a sample processing / QC checklist in the TA-59 data packages for the uranium analysis is considered a good practice and meets the intent of the ASA for certain data package parameter documentation. It is recommended that data packages generated by TA-48 contain similar documentation forms.

Item 5. CST will develop a process flow of the radiochemistry analysis in order to determine and implement areas of improvement for data production. This will be conducted jointly with appropriate CST groups.
Findings.

Appendix 3 of the CST Bioassay Project Management Plan contains a Bioassay Program Flow Diagram, Version 4 dated May 20, 1998. Revision 1 of the Flow Diagram dated September 15, 1998 was issued under Revision 1 to the CST Bioassay Project Management Plan dated September 23, 1998. An earlier October 31, 1997 version of a narrative process flow description was issued by Peggy Gautier, CST-3, in a memo to Alverton Elliott entitled "Response to Price Anderson Noncompliance Report on LANL Bioassay Program (NTS-ALO-LA-LANL-1997-003)." In addition, this memo also defined process improvements that were to be taken to reduce the plutonium bioassay sample backlog in a fast and cost effective manner. The original and revision 1 of the CST Bioassay Project Process Flow diagram are of sufficient process and functional responsibility detail to ascertain a clear grasp of the "origin (worker)-collection/sample management-submittal-processing-raw data generation-data reduction-analytical data packages / reports - QA & records management" of sample flow through the ESH-12 and CST organizations. The use of the flow diagram should facilitate the design, maintenance and improvement of the data production process. The September 15, 1998 revision was an improvement over the original process flow diagram for two reasons: the specific names of individuals responsible for the flow elements were removed and a decision tree was included that more represented the actual contingencies available for the processing of Pu-239 by the TIMS method. This flow diagram will be revised to reflect changes in the Bioassay Project Management Plan, analytical procedure, sample processing flow or decision trees generated from quality or production performance criteria.

Item 6. LANL will initiate action to meet the requirements of the DOE Accreditation Program for Radiobioassay (DOELAP). ESH-12 initiated a Request for Quote (RFQ) to assist in meeting the DOELAP requirements. This service will include the assessment of current operations and the development of a Plan/Program that will meet the DOELAP accreditation standards. This assessment will also be used to identify and eliminate any weakness found in the program. This RFQ was issued and a contractor has been engaged effective October 1, 1997. Responsible Group: ESH-12.
Findings.
Substantive effort has been expended relative to preparing LANL for participating in the DOE Accreditation Program for Radiobioassay. On October 6, 1997, Sonalysts, Inc, under contract with ESH-12, initiated a program assessment of the ESH / CST dosimetry programs and services as related to the DOELAP accreditation requirements. Peggy Gautier, CST-3, issued a letter to Tansy Taylor, DOE-RESL, dated October 23, 1997 stating LANL interest in pursuing DOELAP accreditation for 1998. A Project Management Plan for the Dosimetry Services Accreditation Plan was prepared by Sonalysts, Inc. dated November 4, 1997. A draft of the DOE Technical Standard entitled "The Department of Energy Laboratory Accreditation Program for Radiobioassay," dated December 1996 was obtained and a cross walk (cross reference) of existing ESH and CST programs, procedures and processes to the draft DOELAP requirements was developed by Sandra Wagner. The cross walk matrix summary was dated September 23, 1998. An implementation plan assigning priority and staff responsibilities should be developed to address new requirements or programs not currently established or maintained. A formal application for DOELAP accreditation for indirect radiobioassay has been filed by Sandra Wagner, CST Bioassay Project Leader during the last week of September 1998. Completion of the application by Ms. Wagner was dated September 25, 1998. The application shall be forwarded to the Director of Occupation Safety and Health Division, DOE-Albuquerque Office for authorization and signature. Processing of the application and scheduling of a DOELAP evaluation are pending. Sandra Wagner issued the status and a schedule relative to LANLÕs participation in the DOELAP in vitro radioassay program at the September 24, 1998 pre-assessment meeting. A formal document to file defining the proposed schedule to address the DOELAP process should be written. The schedule presented at the meeting included: C submit DOELAP application by 9/30/98, C CST participation in DOELAP PE sample testing round early in 1999, C conduct an internal "practice" DOELAP audit the summer of 1999, C formal DOELAP audit scheduled for fall 1999, and C upgrade program to meet DOELAP requirements over the coming year.

Item 7. An independent assessment of the LANL bioassay program will be performed to determine effectiveness of the above corrective actions.

Findings.

This assessment addresses this corrective action item.
Item 9. CST-9 and CST-11 have voluntarily participated in the analysis of urine samples spiked with radionuclides that were prepared and distributed by the Intercomparison Studies Group at Oak Ridge National Laboratory. All the results for 1997 met the acceptance criteria. During FY98, CST-11 will analyze four sets for Pu from Oak Ridge and CST-9 will participate in the NIST Radiochemistry Intercomparison Program for urine and fecal samples.

Findings.

CST-9 and CST-11 participated in the Oak Ridge Urine Bioassay Performance Evaluation Studies (ORUBPES) during FY97 and FY98. This program uses single blind natural urine samples that have been spiked with the radionuclides of interest. All radionuclides reported to ESH in the LANL Bioassay Program were evaluated using RAS and TIMS methods at different times. Acceptable bias performance for the testing program (-25% to + 50%) is the same as the Performance Testing Criteria recommended in ANSI N13.30-1996. The Oak Ridge Testing program evaluated the precision performance criterion (± 40%) for the CST operations on a limited basis. Performance results for the five performance tests conducted in FY97 and the one performance test for FY98 were reviewed. For the ORUBPES program, the bias for the TRUs at higher levels (~ dpm/L) by RAS and TIMS was typically <20%. All results would meet ANSI N13.30 performance guidance for bias. A definite continued negative bias exists in the performance for Pu-239, Pu-239 and Am-241. At lower levels of Pu-239 (~ 3 to 12 fCi/sample) the TIMS analyses of duplicate samples had an average bias of + 22.5% and 3.2%, respectively. Acceptable performance for the analysis of H-3 and natural uranium by RAS was observed (H-3 bias < ± 9%; Unat bias < ± 19%). Overall CSTÕs performance in this single blind PE program was satisfactory and would meet ANSI N13.30-1996 and draft DOELAP requirements. LANL participated in the 1998 round of the NIST Radiochemistry Intercomparison Program (NRIP98-SU) for Pu-238, Am-241, U-238 and Sr-90 in a synthetic urine matrix. LANL did not report results for Pu-238. NIST reported a -17% and -10% bias for Am-241 and Sr-90, respectively. A small +1% bias was reported for U-238. The reported precision of the analyses ranged from 4% (2 sigma) for U-238 to 24% (2 sigma) for Sr-90. LANLÕs performance for Am-241, U-238 and Sr-90 analyses met the N13.30 acceptance criteria for bias and precision. CSTÕs performance in the pilot studies for the DOELAP in vitro radiobioassay, as administered by Tansy Taylor of the DOE-Radiological and Environmental Sciences Laboratory, was reviewed for the periods covering 1989, 93, 94, 95, 96 and 1997. Due to the time restrictions, only a random sampling of the DOELAP Performance reports were reviewed. Of the more recent intercomparison studies, only the 1997 results for the fecal sample were reviewed. LANL did not participate in the 1998 DOELAP intercomparison program. LANLÕs 1997 performance relative to the fecal analysis was acceptable for Am-241 but unacceptable for Pu. The submitted data for Pu in feces analyses was limited due to processing problems. The Pu in feces results did not meet the bias acceptance criterion for DOELAP (-25% to + 50%). CST participation in the 1996 DOELAP test round (OCS-RESL-96-151) for urine was very satisfactory: Pu isotope biases < 4%; Am-241 bias < 9%; and precision for the TRUs < 11%. CST had poorer performance for the 1993 (OID-RESL-93-035) pilot study for Pu: Bias ~ - 75%. The performance of CST in the external performance evaluation programs should be provided to ESH-12 on a timely basis. As presented in the findings for Corrective Action Item 2, there should be requirements in the ASA for CST to routinely (semiannual or annual) provide a summary reporting to ESH of internal batch QC results and to have a feedback mechanism for the results of all external QC or PE programs. CST should look into the development of a quality indicator database for internal batch QC results that can be made available to ESH on a full time, read-only access basis. In addition, ESH and CST should jointly develop quality corrective action implementation set points for the internal batch QC results.

Item 10. The following events have resulted in a revisit of the effectiveness of the corrective actions defined above (original seven corrective action items)

1. On February 2, 1997, there was an integration of some of the programs and groups between NMT and CST divisions. This has had a direct impact on the "Responsibilities and Authorities Document" noted in Corrective Action #1 as well as the wording in the "Analytical Support Agreement" dated November 3, 1997. Both of these documents are in the process of being updated to reflect new organization structures as well as internal document clarifications.

Findings:

The issuances of the CST Bioassay Project Management Plan, effective date of July 14, 1998, with revision 1 dated September 23, 1998 and the CST Division and ESH-12 Analytical Services Agreement FY 1998, Contract # ESH-12-ASH-98.01, dated November 3, 1997 with revision 1 dates September 3, 1998 fully addresses this item. This portion of the corrective action is considered closed.

2. On March 9, 1998, the CST Division Director appointed a full time CST Bioassay Project Leader for the chemical analysis portion of the LANL bioassay program. This individual has reviewed the entire CST bioassay program and is in the process of developing a Project Management Plan (PMP). Part of the PMP will update the CST Bioassay Process Flow (Corrective Action #5) as well as establishing a time line for the DOELAP accreditation process (Corrective Action #6).

Findings:

The CST Bioassay Project Management Plan has been issued, effective date of July 14, 1998, with revision 1 dated September 23, 1998. Appendix 3 of the CST Bioassay Project Management Plan contains a Bioassay Program Flow Diagram, Version 4 dated May 20, 1998. Revision 1 of the Flow Diagram dated September 15, 1998 was issued under Revision 1 to the CST Bioassay Project Management Plan dated September 23, 1998. For further information, the findings for Corrective Action Item 5 should be reviewed. Sandra Wagner issued the status and a schedule relative to LANLÕs participation in the DOELAP in vitro radioassay program at the September 24, 1998 pre-assessment meeting. A formal document to file defining the proposed schedule to address the DOELAP process should be written This portion of the corrective action is considered closed.

3. "A Friendly Assessment" of the LANL Bioassay Program was conducted on March 11 and 12th, 1998. This assessment confirmed that the corrective actions had been completed, however, areas were identified that could strengthen the program. These improvements to the system are being worked as part of the PMP. The update of the "Responsibilities and Authorities Document" and "Analytical Support Agreement" and the development of the Project Management Plan will be completed before the Independent Assessment (Corrective Action #7). It is anticipated that any findings/observations identified as part of the assessment will be incorporated into the PMP as appropriate.

Findings:

The issuances of the CST Bioassay Project Management Plan, effective date of July 14, 1998, with revision 1 dated September 23, 1998 and the CST Division and ESH-12 Analytical Services Agreement FY 1998, Contract # ESH-12-ASH-98.01, dated November 3, 1997 with revision 1 dates September 3, 1998 fully addresses this item. Recommendations provided in this assessment should be addressed through either updates in existing documents and programs or the development of new programs or plans. Action items should be identified and assigned with a completion schedule to staff for completion. A computerized tracking system would facilitate such a process. Follow up pre-scheduled status meeting should be held and reports issued.